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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,237	11/10/2000	Philip Henry Coelho	30195-pa	3030

37095 7590 04/25/2005

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/709,237

Applicant(s)

COELHO ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-12, 14, 15 and 19-40 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 14, 15 and 19-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

RD

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 10-12, 14, 15 and 19-40 are pending.

Applicants' amendment filed February 14, 2005 is acknowledged. Applicant's response has been fully considered. Claims 10 and 19 have been amended, claims 1-9 and 16-18 have been cancelled, and new claims 20-40 have been added. Claim 12 is a non-elected invention, thus withdrawn from consideration. Therefore, claims 10-11, 14, 15 and 19-40 are examined.

Note that claim 12 is not cited in the Listing of claims.

### **Objection Withdrawn**

2. The previous objection of specification, regarding the term "ETOH", is withdrawn in view of applicant's amendment to the specification, and applicant's response at page 9 in the amendment filed February 14, 2005.
3. The previous objection of claims 10, 11, 14, 15 and 19, regarding the term "ETOH", is withdrawn in view of applicant's amendment to the specification, and applicant's response at page 10 in the amendment filed February 14, 2005.

### **Rejection Withdrawn**

### ***Claim Rejections - 35 USC § 112***

4. The previous rejection of claims 9 and 16-18 under 35 U. S. C. 102(b) as being anticipated by Boss, Jr. (U. S. Patent 5,591,444), is withdrawn in view of applicant's cancellation of the claim, and applicant's response at page 10 in the amendment filed February 14, 2005.
5. The previous rejection of claims 9 and 16-18 under 35 U. S. C. 102(b) as being anticipated by Baugh *et al.* (U. S. Patent 6,444,228), is withdrawn in view of applicant's

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cancellation of the claim, and applicant's response at page 10 in the amendment filed February 14, 2005.

### *Informalities*

The disclosure is objected to because of the following informalities:

6. The amended specification filed February 14, 2005 cites "the final calcium chloride concentration is at 0.023  $\mu$ M (250 mM) calcium chloride" and "The range of final calcium chloride concentration between 0.011  $\mu$ M (125 mM) and 0.045  $\mu$ M (500 mM)" in the description of Fig. 6 (see pages 3-4 of the response). Applicant indicates the concentration in millimolar units are the original reagent concentration and the concentration in micromolar units are final concentration (page 9 of the response), however, these statements are not cited in the specification. Appropriate clarification is required.

7. Figs. 5 and 6 are objected to because of the term " $\text{CaCl}_2 = 0.23 \mu\text{m}$ " (in Fig. 5) and "(0.011  $\mu$ M) of 125 mM  $\text{CaCl}_2$ ; (0.023  $\mu$ M) of 250 mM  $\text{CaCl}_2$ ; (0.045  $\mu$ M) of 500 mM  $\text{CaCl}_2$ " (in Fig. 6; see paragraph 3 of the previous Office Action). Appropriate correction is required.

Please submit the corrected drawings.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 10-11, 14, 15 and 19-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10-11, 14, 15 and 19-40 are directed to a thrombin composition free of fibrin clots, consisting essentially of plasma, EtOH and  $\text{CaCl}_2$  (or a source of calcium ion). The specification indicates the procedure of invention is comprised of three steps, the first two of which should occur at the same time: (1). Preparing a fraction enriched in prothrombin by use of Ethanol to substantially enhance the concentration of prothrombin and at the same time remove or denature naturally occurring ingredients within plasma; (2). Adding calcium ions to the enriched prothrombin solution and briefly agitating the solution to convert the pro-thrombin to stable, long term thrombin; (3). Expressing the thrombin solution through a filter to remove particulate matter (page 8 of the specification). Thus, the specification only describes the preparation of thrombin from plasma by concentrating the prothrombin fraction with EtOH, where the plasma proteins have been removed, and converting prothrombin to thrombin with  $\text{CaCl}_2$ , it does not describe a thrombin composition free of fibrin clots, where the composition contains plasma (including all plasma proteins such as fibrinogen), EtOH and calcium ion. Furthermore, the specification does not disclose the thrombin composition is in tangential relationship with a glass surface (see paragraph 11 below). The lack of description of a thrombin composition free of fibrin clots, consisting essentially of plasma, EtOH and  $\text{CaCl}_2$  (or a source of calcium ion) in the original specification and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full,

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clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

This is a new matter Rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 22-26 and 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 22-25 and 34-37 are indefinite because of the use of the term "clotting speed". The cited term renders the claim indefinite, it is not clear how the "clotting speed" has "seconds" as its unit, the word "speed" is a measure of the rate of motion. Use of the term "clotting time" is suggested.

11. Claims 26 and 38 are indefinite because of the use of the term "tangential relationship with a glass surface". The cited term renders the claim indefinite, it is not clear what the term means.

***Conclusion***

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM  
PATENT EXAMINER**

CMK  
April 22, 2005